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CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

Summary Comments of the Consumer Healthcare Products Association Relating to FDA's July 26th Public Meeting on Bar Code Label Requirements for Human Drug Products July 12, 2002

A comprehensive solution to medication error is a long-term vision requiring cooperative efforts by those segments of the drug distribution and dispensing system that will be affected. Over-the-counter (OTC) drug products are used principally by consumers in a retail self-care environment, but also in some circumstances by health professionals for their patients. Recognizing the very different uses of OTCs in these two settings, CHPA has the following summary comments, and will make more detailed remarks at FDA's public hearing scheduled for July 26th.

(a) We understand the information to date has focused on medication errors relating to prescription drugs. Before turning to a solution involving OTCs, it is important to establish a well-developed evidence-based description of the issues related to OTC use in the institutional setting. Understanding these issues would be helpful in designing solutions, and CHPA is interested in helping to consider ways to create useful and practicable solutions to medication errors involving OTCs.

(b) It is unlikely that the use of bar codes by consumers in the non-institutional self-care setting is reasonably feasible or preferred over print labeling. Current OTC print labeling contains all the essential information for safe and effective use of OTC drug products, including active ingredients, directions for usage, warnings (contraindicated medications and contraindicated medical conditions, allergy warnings), lot, expiration and storage information. In fact, current regulations under the OTC Drug Facts rule mandates the listing of all active ingredients (including their strengths) as the first section on the product labeling on all OTC drug products.

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(c) Currently all OTC drug products intended for retail sale bear a bar code (Universal Product Code, or UPC) on the outer container as a means to track channels of distribution, inventory management, and sales by channel. If use of the UPC to address medication errors changes the code's current intended use or its efficiency of use, it will

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result in significant barriers in distribution channels. Also, we are not sure that the addition of a bar code in addition to the UPC on the package is either feasible or that institutions will have the appropriate tools to read this code and convert the information into a usable format that will reduce medication errors. Conversion of bar code information will require the development and maintenance of a standardized, uniform dictionary that must be maintained and updated on a routine basis in order for the coded information to be useful. We are not aware of any existing system exists for this translation of the information. Furthermore, any proposed solution needs to be organized on a national level, to ensure systems compatibility and applicability. Special attention needs to be given to any proposed hardware/software solutions to guarantee that they do not actually create additional unforeseen problems, mix-ups, or confusion and that they are compatible with existing institutional data systems. Nevertheless, if there are ways to take the current UPC-based system and efficiently apply it to the issue of medication errors, then we are open to and interested in exploring such possibilities.

(d) Finally, CHPA concurs with the written position of National Coordinating Council for Medication Error Reporting and Prevention that any changes in bar coding requirements should be done incrementally and with careful thought as to feasibility, practicality, and cost-benefit weighing patient protection, efficiency of proposed systems, and scope.

CHPA looks forward to an opportunity to engage in further dialogue on this subject with interested parties.

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WS/OTClabeling/BarCodes/SummaryCommentsBarCodes-FDA Call for Info [final]:7-12-02

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